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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/990,499
Filing Date: November 21, 2001
Appellant(s): BAKSHI ET AL.

Date mailed 6/22/04

Philippe Durette
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12 April 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because all of the claims are drawn to the treatment of erectile dysfunction in a male subject comprising administration to a subject in need thereof a therapeutically effective amount of a compound which is a selective agonist of

the human MC-4R. The difference between the claims is claims 39-73 do not require oral treatment while claims 74-75 do require oral administration. However, claims 39-73 encompass the oral treatment as well as other treatment options. Oral treatment is the most widely used for treatment of similar dysfunctions.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or

patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. The rejection of claims 39-75 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,350,760, is ***upheld***. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the patent are fully encompassed by the instant claims. Also, the compound of line 40 column 82 of the patent is the cis/trans stereoisomer of the elected species.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 39-75 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is ***upheld***. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to choose a compound that is outside the scope of the instant formula (I) (see page 7). No structural characteristics of an agonist are provided nor is there any indication that applicant had possession of any such agonist other than the compounds of

formula (I) which have already been patented (see the above double patenting rejection). The specification fails to disclose any particular structure for the claimed receptor agonists. Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention, the claims fail to comply with the written description requirement.

5. The rejection of claims 39-75 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is ***upheld***. The specification does not enable the ordinary artisan to choose a compound that is other than patented in the parent case, namely a substituted isoquinoline. The entire specification is drawn to substituted isoquinoline compounds of formula (I) that are MC-4R agonists. There is no teaching in the specification that would lead one of ordinary skill in the art to compounds other than formula (I). Without a teaching of what other compounds to pursue, the specification is seen to be lacking in enablement for the instant claims. Without guidance, the instant specification is an invitation to test any and all known and unknown compounds for their ability to bind selectively and be agonists of MC-4R.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims: The claims are drawn to treatment of sexual dysfunction in a male subject with any compound that is a MC-4R agonist.
2) The nature of the invention: The invention is drawn to treatment of male erectile dysfunction by using a MC-4R agonist wherein the binding of the compound to MC-4R is characterized by an IC50 of less than 30 nanomolar and the binding of the compound to the human MC-1R is characterized by an IC50 greater than 30 nM.
3) The state of the prior art: The prior art discusses treating male erectile dysfunction by using certain families of compounds that are MC-4R, MC-3R, MC-2R, MC-1R, and MC-5R agonists. However, the art is silent about what other compounds or families of compounds might be MC-4R agonists.
5) The level of predictability in the art: It has not been shown that there is any level of predictability in the art.
6) The amount of direction provided by the inventor: The inventor has provided direction only for the compounds of formula (I) treating male erectile dysfunction. However, there is no direction provided by the inventor to treat male erectile dysfunctions with any compound that is other than a compound of formula (I).
7) The existence of working examples: The only working examples of MC-4R agonists are of formula (I). The specification does not provide any other working examples other than the compounds of formula (I) that have already been patented.
8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The experimentation needed to make or use the instant invention is undue. There is no guidance of what kind of compound to choose other than of formula (I) to be a MC-4R agonist. The ordinary artisan would be forced to pick compounds at random from all known and unknown compounds to test them randomly to see if they are MC-4R agonists having the other parameters that are disclosed in the claims. This is very extensive and undue experimentation.

Taking these into consideration, it is not seen where the instant specification enables the ordinary artisan to make and/or use the instant invention.

Further, the instant specification does not provide any guidance with respect to how to choose a compound outside of the scope of the formula (I) that would fulfill the requirements for the instant claims. There is no description of the identifying characteristics for recognizing that a compound is a candidate for the instant claims. No structural characteristics of such compounds are provided, nor is there any indication that applicant has possession of any such compound outside of the compounds of formula (I). The specification fails to disclose any particular structure for the compound that would treat male erectile dysfunction other than formula (I). The specification does not provide any guidance or any working examples in this unpredictable art, and thus the artisan would have been unable to prepare the claimed treatment. An assay for finding a product is not equivalent to a positive recitation of how to make a product. These claims fail to meet the enablement requirement for the "how to make" prong of 35 USC 112, first paragraph.

Applicants argue that direction and guidance is given. Critical inventive parameters of selective activation of the MC-4R receptor is given. How to identify compounds that properly bind and function as agonists and how to evaluate their therapeutic properties in models is given.

However, an assay for finding a product is not equivalent to a positive recitation of how to make a product. No structural characteristics are provided of compounds that meet the instant claims. The compounds of formula (I) and how to treat using these compounds have already been patented in US Patent #6,350,760. Other than these compounds of formula (I), no other enablement is given. Applicant has not shown that they are in possession of the claimed invention.

(11) Response to Argument

Issue 1: Rejection of claims 39-75 under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

1. Applicant argues that although applicant describes the compounds of formula (I) as being selective MC-4R agonists, such compounds are merely representative of other structural types known in the art that may also be selective agonists.

However, it is the Examiner's position that applicant describes the compounds of formula (I) as being MC-4R agonists. No other structural types of selective agonists have been identified in the instant specification. Only testing procedures that any compounds could be put into to determine if that compound could be a selective agonist and fit within the scope of the instant claims.

2. Applicant argues that they have discovered a relationship in the art between the function of binding to the family of G-protein-coupled receptors to which MC-4R belongs and the structure of potential ligands having affinity for such receptors.

However, it is the Examiner's position that applicant has not claimed any of these potential ligands that have affinity for such receptors. Only the formula (I) has been identified. Everything else falls within a general idea that may or may not be workable.

3. Applicant argues that the 4-substituted piperidines are merely one class of such privileged structure scaffolds known in the G-protein-linked receptor art. Other structurally diverse variants outside the scope of formula (I) make up a rich pool of compounds that should be evaluated according to the methods described in the instant application.

However, it is the Examiner's position that the only structure having written description in the instant specification is formula (I). All other structures have not been described in any way that would put them into the knowledge of the ordinary artisan.

4. Applicant argues that the guidance for selection of compounds beyond those of formula (I) that would fulfill the requirements of the instant claims continues to be provided by the art. Therefore, there exists in the art definite structural characteristics for recognizing candidate compounds with the potential to function as selective MC-4R agonists and thereby providing clear guidance with respect to how to choose a compound outside the scope of formula (I).

However, it is the Examiner's position that to fulfill the requirements of written description, the art definite structural characteristics need to be provided by the instant specification and not the art as to how to choose a compound outside the formula (I).

Issue 2: Rejection of claims 39-75 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement.

1. Applicant argues that the Examiner has misconstrued the nature of Appellants' invention. Applicant has not invented any particular chemical compound, a class of structurally defined compounds, or methods of using a particular chemical compound or class of structurally defined compounds.

However, it is the Examiner's position that Applicant is correct. Applicant has not invented any particular chemical compounds or class of structurally defined compounds outside of formula (I) or methods of using a particular class of structurally defined compounds.

2. Applicant argues that they have discovered a specific physiological function for the human MC-4R agonism and the induction of penile erections.

However, it is the Examiner's position that Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable". The instant claims are drawn to general ideas that Applicant has failed to give an enabling disclosure to compounds other than of formula (I).

3. Applicant argues that they have not invented compounds but a novel method of treating erective dysfunction in human males.

However, it is the Examiner's position that Applicant has not invented a novel method of treating anything but has instead found a link between MC-4R agonism and erective dysfunction in human males. The treatment method is drawn to the compounds of formula (I) only.

4. Applicant argues that the "critical reaction parameter" for the method claims is the function of selective activation of the human MC-4R and the instant specification clearly sets out a roadmap for the skilled artisan in the pharmacological arts to follow in order to identify compounds which have this selective binding ability.

However, it is the Examiner's position that this is an idea that has linked the MC-4R agonism to treating erective dysfunction in human males. The discovery of a link between agonism and treatment does not equate to the enabling disclosure of an invention.

5. Applicant argues that the ready availability of automated methods for drug screening allows for the routine screening of large chemical collections and libraries of chemical compounds to identify compounds with defined biological properties.

However, it is the Examiner's position that the instant specification provides no guidance outside of the compounds of formula (I) from which to start the search using these automated methods for drug screening. The ordinary artisan would have to screen each and every drug in their large chemical collections and libraries to test each

and every one to see if that compound had the properties that are instantly claimed. Applicant provides no guidance as to what kinds of compounds might work. Applicant provides no guidance as to what kinds of linkages might needed to be contained in those compounds to fit within the scope of the instant claims. This leads to undue experimentation.

6. Applicant argues that the how to make and how to use compounds within the scope of the instant claims is clearly given in the instant specification.

However, it is the Examiner's position that Applicant does not teach "how to make" the compounds that fulfill the metes and bounds of the instant claims.

7. Applicant argues that the critical or essential method parameters which are necessary to practice the invention is merely exemplified by the compounds of formula (I).

However, it is the Examiner's position that the only critical and essential method parameters given and enabled by the instant specification are drawn to the compounds of formula (I).

8. Applicant argues that once a compound having the receptor binding and functional properties within the parameters of the instant claims is identified, the preparation of the pharmaceutical composition for systemic administration can be accomplished following the methods described in the instant application.

However, it is the Examiner's position that it is the finding of the compound that has the receptor binding and functional properties that are within the parameters of the

instant claims which is undue experimentation. The ordinary artisan would have to test any compound that could be tested with a hit or miss trial to determine if the compound could possibly fit within the scope of the instant claims.

9. Applicant argues that other functional claims have been patented previously by the United States Patent Office.

However, it is the Examiner's position that the merits of those cases are not before the Examiner or the Board, only the present case is before the Examiner and the Board. The circumstances of those patents are not known.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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dms
June 15, 2004

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